No. 11832

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

CHESTER WALKER COLGROVE, Trading and Doing Business Under the Firm Name of COLUSA REMEDY COMPANY, and COLUSA REMEDY COMPANY, a corporation,

Appellants,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLEE'S BRIEF.

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APPELLEE'S BRIEF.

I.

Statement of Jurisdiction.

The District Court had jurisdiction to try the defendants pursuant to Title 21, U. S. C., Section 332(b), and Title 28, U. S. C., Sections 385 and 387.

Under Title 28, U. S. C., Sections 225 (a) and (d), this Court has authority to review the judgments of the District Court.

II.

Statutory Provisions Involved.

Federal Food, Drug, and Cosmetic Act.

"Section 301. Prohibited acts [21 U. S. C. 331.]

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of . . . drug . . . that is misbranded."

"Section 201. Definitions; generally. [21 U. S. C. 321.]

For the purposes of this chapter—

(g) The term 'drug' means . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . ."

"Section 502. Misbranded drugs and devices. [21 U. S. C. 352.]

A drug shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

. . . . . .

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . ."

"Section 302. Injunction proceedings—Jurisdiction of courts. [21 U. S. C. 332.]

(a) The district courts of the United States . . . shall have jurisdiction, for cause shown . . . to restrain violations of section 301 [21 U. S. C. 331] . . . .

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by court, or upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 387 of Title 28, as amended."

Other Statutes Relating to Criminal Contempt.

Title 28, U. S. C.

"Section 385. Administration of oaths; contempts.

The courts of the United States shall have power . . . to punish, by fine or imprisonment, at the discretion of the court, contempts of their authority. Such power to punish contempts shall not be construed to extend to any cases except . . . the disobedience . . . by any party . . . to any lawful writ, process, order, rule, degree, or command of the said courts."

Federal Rules of Criminal Procedure.

"Rule 42. Criminal Contempt.

. . . . . .

(b) Disposition Upon Notice and Hearing. A criminal contempt except as provided in subdivision (a) of this rule shall be prosecuted on notice. The notice shall state the time and place of hearing, allow-

ing a reasonable time for the preparation of the defense, and shall state the essential facts constituting the criminal contempt charged and describe it as such. The notice shall be given orally by the judge in open court in the presence of the defendant or, on application of the United States attorney or of an attorney appointed by the court for that purpose, by an order to show cause or an order of arrest. The defendant is entitled to a trial by jury in any case in which an act of Congress so provides. He is entitled to admission to bail as provided in these rules. If the contempt charge involves disrespect to or criticism of a judge, that judge is disqualified from presiding at the trial or hearing except with the defendant's consent. Upon a verdict or finding of guilt the court shall enter an order fixing the punishment."

Regulations Promulgated by Federal Security Administrator.

Title 21, Code of Federal Regulations, Cumulative Supplement, page 5224, as amended by 1946 Supplement, page 2952.

"§2.106. Drugs and devices; directions for use.

(a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used;

(2) Quantity of dose (including quantities for persons of different ages and different physical conditions);

(3) Frequency of administration or application;

(4) Duration of administration or application;

(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor);

(6) Route or method of administration or application; or

(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process)."

III.
Statement of the Facts.

In order that this Court may consider this case in its proper setting, it is necessary to outline the history of defendants' operations as they appear in the Record and in other sources which the Court may judicially notice.

For a number of years, defendants have been marketing two products on an extensive national scale, one labeled Colusa Natural Oil, and the other designated as Colusa Natural Oil in capsules. [R. 59-60; see also R. 31-32 (part of Def. Ex. A) enumerating 58 newspapers in which the products have been advertised.]

The labeling of these products declares that they consist of a natural unrefined petroleum oil. [R. 22.] Throughout the years, defendants have been offering this oil to the public as beneficial and efficacious in the treatment and cure of a variety of skin diseases including psoriasis, eczema, poison ivy, poison oak, athlete's foot,

leg ulcers, acne, itch, open sores, burns, cuts, ringworm, varicose ulcers, bed sores, piles, and scaley red face. [R. 20, Pl. Ex. 1; *Empire Oil & Gas Corporation et al. v. United States,* 136 F. 2d 868, 869 (C. C. A. 9, 1943).]

Investigations and controlled clinical studies have demonstrated that Colusa Natural Oil in capsules or otherwise is simply crude oil and worthless in the treatment of the skin diseases for which it was offered, and may under some circumstances even produce a harmful effect. (*United States v. 9 Bottles . . . "Colusa Natural Oil,"* 78 Fed. Supp. 721 (N. D. Iowa, Nov. 26, 1947).)

To prevent continued marketing of this oil, the Government has successfully resorted to many-pronged action under the Federal Food, Drug, and Cosmetic Act including seizure, criminal prosecution, injunction, and criminal contempt.

Since 1940, the District Courts in practically every judicial district have effected large scale seizures and condemnations of these products wherever they could be found. (See *Drugs and Devices Notices of Judgment* issued by the Federal Security Administrator pursuant to 21 U. S. C., 375(a), especially Nos. 1384 and 2087 which alone comprise 110 different actions.)[1] . Most of these actions resulted in condemnation by default. A group of such consolidated seizure actions was recently tried in the Northern District of Iowa and resulted in the Court's condemning the products and unequivocally declaring their worthlessness for the disease conditions for which they were then offered in their labeling, namely, psoriasis,

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[1]Judicial notice has been taken of such Notices of Judgment in *Libby, McNeill & Libby v. United States,* 148 F. 2d 71, 73, footnote 3 (C. C. A. 2, 1945).

eczema, athlete's foot, and leg ulcers. (*United States v. 9 Bottles . . . "Colusa Natural Oil," supra.*) Colusa Remedy Company has noted an appeal in that case but at this writing has not yet perfected it.

In the meantime, seizure action alone having proved ineffective to compel defendants to desist from misbranding their products, the United States had proceeded in 1942 by way of criminal prosecution in the Northern District of California against defendant Chester Walker Colgrove and the Empire Oil and Gas Company. (The latter company, controlled by defendant Colgrove, was subsequently metamorphosed into Colusa Remedy Co. by said defendant.) There the issue was whether the labeling of the oil was false or misleading in representing it as useful in the treatment of eczema, psoriasis, acne, ringworm, athlete's foot, burns, cuts, poison ivy, and poison oak. After a jury trial, defendants were convicted. This Court reversed on the ground that a witness produced by defendants was competent to answer certain questions ruled out by the trial court. (*Empire Oil & Gas Corp. et al. v. United States, supra.*) Upon remand, defendants pleaded *nolo contendere.* Defendant Colgrove was fined $1500 and the defendant corporation was fined $3. In addition, defendant Colgrove was sentenced to 6 months in jail, such sentence to terminate on the payment of the fine. (*Drug and Device Notice of Judgment* No. 1040.)

Apparently, fines and continuous confiscation of merchandise were insufficient to cause defendants to discontinue a lucrative interstate business. [R. 59.] As a result of their search for a loophole in the law [R. 59, 61-63], they changed the labeling of their products so that in 1945 the labeling failed to mention *any* disease conditions for which the products were offered. [Pl. Ex. 3, R. 23.] The

new promotional line was for the defendants to proclaim the alleged remarkable attributes of their products in large newspaper advertisements throughout the country. [R. 59, Pl. Ex. 1, R. 21.]

Theretofore, enforcement actions had been based upon the charge that the oil was misbranded because its *labeling* bore false and misleading therapeutic claims in violation of 21 U. S. C. 352(a). Defendants' therapeutic claims were now confined to *newspaper advertising.*

However, under 21 U. S. C., 352(f)(1), a drug is deemed misbranded if its *labeling* fails to bear adequate directions for use. Upon Complaint by the United States, the District Court for the Southern District of California found that the new *labeling* utilized by defendants failed to bear adequate directions for use in the conditions for which it was prescribed, recommended, and suggested in defendants' advertising. The Court then issued a preliminary injunction on February 24, 1947, restraining the defendants from shipping their oil interstate

> "without a label containing specific directions for the use of such product in the treatment of all conditions, ills and diseases for which such product is prescribed, recommended, and suggested, in the advertising material disseminated or sponsored by or on behalf of the defendants or either of them; which directions shall include the quantity of the dose (including quantities for different ages and different physical conditions) to be taken or applied in the treatment of each of such conditions, ills and diseases, as well as the recommended frequency and duration of administration or application of such dosage."

On April 23, 1947, *with the written and signed consent of the defendants,* the Court issued a permanent injunction using the identical language quoted above, except that the words "adequate directions" were substituted for the words "specific directions." [R. 2, 3; Pl. Ex. 4, R. 23-24.]

Defendants understood the requirement of the injunctions that the labels on their products had to state the disease conditions for which they were offered in the advertising. [R. 59.] They devised a new label which stated that the Colusa Natural Oil was "intended for use in treatment of Psoriasis, Eczema, Athlete's Foot and Leg Ulcers" [R. 22], whereas their previous label had mentioned no disease conditions at all. [R. 23.]

Defendants then changed their advertising to highlight the same four disease conditions which they now listed in their new label, namely, psoriasis, eczema, athlete's foot, and leg ulcers. [Pl. Ex. 1, R. 20.] However, the body of the advertising continued as before to give glowing reports of benefits derived in these and eight other conditions. [Pl. Ex. 1, R. 20.] Thus, under the heading "SUMMARY OF CLINICAL REPORTS ON 28 CASES," there is a quotation of a report allegedly from a Texas doctor that with this oil he had completely cured patients suffering from psoriasis, eczema, leg ulcers, athlete's foot, *and poison ivy or oak.*

Similarly, under the heading "THOUSANDS OF DOCTORS ARE COLUSA CUSTOMERS—EXCERPTS FROM A FEW OF THEIR REPORTS," there are alleged quotations describing cures in the following diseases: eczema, *poison ivy,* athlete's foot, leg ulcers, *bed sore, burns,* psoriasis, *acne, ringworm.*

Under the heading "EXCERPTS FROM REPORTS BY DRUGGISTS," preceded by the statement "Druggists in 17 states report 89 stubborn cases where Colusa succeeded after other medicines and doctoring failed," there are reports of cures of eczema, athlete's foot, *scaley red face,* psoriasis, *acne.*

A final heading "THOUSANDS OF USERS WRITE LETTERS OF PRAISE" includes an alleged quotation from a testimonial writer that he had been cured of *itch.*

Counts 1-8 of the instant Criminal Contempt Information are based upon eight different interstate shipments of Colusa Natural Oil bearing the new label recommending the drug for psoriasis, eczema, athlete's foot, and leg ulcers. In conjunction with these shipments, defendants launched an extensive nationwide advertising campaign specifically directing prospective customers to the drug stores that were the consignees of these shipments. These facts are set forth in the Criminal Information, and stipulated to as correct. [R. 2-14, 23-24, 31-2.] As pointed out, the advertising [Pl. Ex. 1, R. 20] held out unequivocal promise of benefit not only in the treatment and cure of psoriasis, eczema, athlete's foot and leg ulcers (the diseases mentioned on the new label), *but also* in the treatment and cure of poison ivy, poison oak, bed sore, burns, acne, ringworm, scaly red face, and itch diseases *not* mentioned on the new label.

Defendants waived their right to a jury trial and to special findings of fact. [R. 25.] After full trial before the Court, defendants were found guilty of criminal con-

tempt as charged in Counts 1-8, and not guilty as to Count 9. [R. 78-79.]

Defendant Colusa Remedy Company was sentenced to pay fines totalling $5000. [R. 35.] Defendant Chester Walker Colgrove was sentenced to pay fines totalling $4000. He was also sentenced to imprisonment for four six-month terms to run consecutively. Execution of all sentences as to defendant Colgrove was suspended for a probationary period of five years, one of the terms of probation being payment of the $4000 fine in installments. [R. 36-38.]

IV.
Questions Involved.

(1) Did the District Court have jurisdiction to issue the preliminary and permanent injunctions?

(2) Is there substantial evidence to support the District Court's judgments holding the defendants guilty of criminal contempt on Counts 1-8 of the Information?

(3) Were defendants deprived of any procedural rights in the contempt proceedings?

(4) If defendants are adjudged guilty of criminal contempt on eight different counts involving eight separate contumacious acts, may the District Court impose a separate sentence of either fine or imprisonment on each of such counts?

V.

ARGUMENT.

From the factual background of this case, it is obvious that the defendants, over the course of the years, have demonstrated considerable ingenuity in their search for a means to circumvent and nullify the Federal Food, Drug, and Cosmetic Act. They have been steadfast in their objective of continuing to make extravagant and baseless therapeutic claims for their Colusa Natural Oil to a gullible segment of the public.[2]

The Government's theory in its enforcement actions against the defendants under the Federal Food, Drug, and Cosmetic Act is divided into two parts. (1) If the labeling of the oil conveys the impression that the oil is therapeutically useful in the treatment of specifically enumerated disease conditions, then, since the oil is worthless, the labeling is false and misleading in violation of 21 U. S. C. 352(a) *United States v. 9 Bottles . . .*; *"Colusa Natural Oil," supra.* (2) If the labeling fails to state any disease conditions for which the oil is offered—the oil being a drug within 21 U. S. C. 321(g)(2) because it is intended for use in the treatment and cure of disease conditions as evidenced by claims in its advertising—then the labeling fails to bear adequate directions for use in violation of 21 U. S. C. 352(f)(1), since it fails to state essential information—*e. g.*, the disease conditions for which it is offered. We will discuss this point at greater length later in the brief.

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[2]Even now, the story recited above is not finished. Still another injunction proceeding is now pending in the Southern District of California (No. 8572 O'C Civil) to prevent further interstate shipments of the same products with yet a new label.

A. Most of Appellants' Brief Deals With Points Not Included in Their Assignment of Errors.

Rule 2(d) of this Court's rules relating to criminal appeals declares that "errors not assigned according to this rule will be disregarded, but the Court, at its option, may notice a plain error not assigned."

Appellants' assignment of errors is its statement of "Points Upon Which Appellant Intends to Rely Upon Appeal." [R. 82-84.] That statement enumerates nine alleged errors of the District Court.

In their brief, however, appellants argue seven points, five of which are not included in their assignment of errors. The five points thus argued are (1) The Original Order of the District Court of the United States Was Not a Valid Order (App. Br. pp. 10-17); (2) The Injunction of the Court Below Was Beyond Its Powers Under the Food and Drug Act (App. Br. pp. 17-19); (3) The Attempt to Control Newspaper Advertising by Injunction Is Contrary to the Constitution of the United States (App. Br. pp. 20-23); (4) There Can Be No More Than One Count for Contempt (App. Br. pp. 34-35); (5) The Sentences Were Excessive (App. Br. p. 36).

Under Rule 37(a)(1) of the Federal Rules of Criminal Procedure, it appears that assignments of error are now abolished. However, appellants did file an assignment of errors and it was upon the basis of that assignment that the Government agreed to having the record printed in its present restricted form, eliminating therefrom a considerable amount of material bearing upon the sentence to be imposed upon defendants and made a part of the record before the District Court at the time of sentencing.

B. The Preliminary and the Permanent Injunctions Issued by the District Court Are Valid.

The permanent injunction in this case was issued by the District Court upon written consent of the appellants. No appeal was taken and no attempt was made by the appellants to modify the injunction or to correct any alleged error therein. Appellants having been convicted of criminal contempt for disobeying the conditions of the preliminary and permanent injunctions, now seek to attack the validity of these injunctions collaterally.

1. Review of an Injunction in a Collateral Proceeding, as Here, Is Restricted to the Question of Whether the District Court Had Jurisdiction Over the Parties and Subject Matter.

It is settled that alleged errors in an injunction "must be corrected by appeal and not by disobedience." *Clarke v. Federal Trade Commission,* 128 F. 2d 542, 543 (C. C. A. 9, 1942).

Of course, if an order is void because issued by a court without jurisdiction of the subject matter or parties litigant, disobedience thereof is not a criminal contempt. *Beauchamp v. United States,* 76 F. 2d 663, 668 (C. C. A. 9, 1935). As we shall point out, there is no doubt that in the instant case the District Court had complete jurisdiction over the parties and subject matter in issuing the injunctions. This being so, the injunctions should have been obeyed, for as this Court said in *Western Fruit Growers v. Gotfried,* 136 F. 2d 98, 100 (C. C. A. 9, 1943):

> ". . . if a court has jurisdiction over both the parties and the subject matter, an order must be obeyed so long as it remains the order of the court."

In *United States v. United Mine Workers of America,* 330 U. S. 258 (1947), the Supreme Court narrowly defined the permissible scope of collateral attack on an injunction in a criminal and civil contempt proceeding based upon violation of the injunction. Even the unconstitutionality of the underlying statute does not authorize violation of an injunction nor protect the violator. On page 293 the Court said:

> ". . . an order issued by a court with jurisdiction over the subject matter and person must be obeyed by the parties until it is reversed by orderly and proper proceedings. *This is true without regard even for the constitutionality of the Act under which the order is issued.* In *Howat v. Kansas,* 258 U. S. 181, 189-90 (1922), this Court said:
>
> > 'An injunction duly issuing out of a court of general jurisdiction with equity powers upon pleadings properly invoking its action, and served upon persons made parties therein and within the jurisdiction, must be obeyed by them however erroneous the action of the court may be, even if the error be in the assumption of the validity of a seeming but void law going to the merits of the case. *It is for the court of first instance to determine the question of the validity of the law, and until its decision is reversed for error by orderly review,* either by itself or by a higher court, *its orders based upon its decisions are to be respected, and disobedience of them is contempt of its lawful authority, to be punished.*' " (Emphasis added.)

As we have mentioned, no appeal was taken from the consent decree of injunction issued in the instant case. The fact that the permanent injunction here was entered by consent has special significance in restricting further the scope of collateral attack. This was emphasized by the Supreme Court in *Swift & Co. v. United States,* 276 U. S. 311, 324 (1928), where defendants were seeking by a collateral proceeding to vacate a consent decree of injunction:

> "But 'a decree, which appears by the record to have been rendered by consent, is always affirmed, without considering the merits of the case.' . . . Where, as here, the attack is not by appeal or by bill of review, but by a motion to vacate, filed more than four years after the entry of the decree, the scope of the inquiry may be even narrower."

Defendants in the *Swift* case also argued, as do appellants here (App. Br. pp. 15-17), that the decree was too vague and general in some of its terms. The Court said in dismissing this objection (p. 328):

> ". . . the defendants by their consent lost the opportunity of raising the question on appeal."

And on page 330, the Court, again stressing the narrow scope of collateral attack upon an injunction, declared:

> "But the Court had jurisdiction of the subject matter and of the parties. And even gross error in the decree would not render it void."

Another argument made in the *Swift* case was that the decree was void because the injunction was not limited to acts in interstate commerce. Appellants here make a similar argument in asserting that the issuance of the injunction was beyond the District Court's power under

the Food and Drug Act in that it assertedly encompassed more in its decree than the statute authorizes. (App. Br. pp. 17-19.) Assuming *arguendo* that this were so, the Supreme Court in rejecting the similar contention made in the *Swift* case has effectively disposed of appellants' argument (p. 331):

> "If the Court, in addition to enjoining acts that were admittedly *interstate,* enjoined some that were wholly *intrastate* and in no way related to the conspiracy to obstruct interstate commerce, it erred; and had the defendants not *waived such error by their consent,* they might have had it corrected on appeal. But the error, if any, does not go to the jurisdiction of the court. *The power to enjoin includes the power to enjoin too much.*" (Emphasis added.)

Appellants here, in attacking the injunctions upon which the contempt convictions are based, do not appear to challenge the fundamental jurisdiction of the District Court over the parties or over the subject matter. In somewhat confusing terms they seem to be charging that the injunction is void because (1) its scope is broader than authorized by the statute, (2) its terms are uncertain and indefinite, and (3) it violates appellants' constitutional rights. (App. Br. pp. 10-23.) *United States v. United Mine Workers, supra,* and *Swift & Co. v. United States, supra,* hereinabove cited and quoted from, establish that appellants may not properly raise these points in this collateral proceeding.

The District Court's fundamental jurisdiction over the subject matter of the injunction stems from its statutory power to restrain certain prohibited acts which are in violation of the Federal Food, Drug, and Cosmetic Act. (21

U. S. C. 332(a).) Among the acts it may restrain is the interstate shipment of a misbranded drug. (21 U. S. C. 331(a).) A drug is deemed misbranded if its labeling fails to bear adequate directions for use. (21 U. S. C. 352(f)(1).) Interpretive regulations of the Federal Security Administrator, promulgated pursuant to 21 U. S. C. 371(a), declare that directions for use are inadequate if there is an omission in whole or in part of directions for use *in all conditions* for which the drug is prescribed, recommended, or suggested in its labeling or in its advertising sponsored by its manufacturer, packer, or distributor. (§2.106(a), Title 21, *Code of Federal Regulations, Cumulative Supplement,* p. 5224, as amended by 1946 Supplement, p. 2952.) Hence, the District Court clearly had jurisdiction of the subject matter involved in the instant injunctions. And jurisdiction over the parties is conceded. [R. 3, 24.]

Furthermore, with respect to the preliminary injunction based upon a hearing and findings, there can be no doubt as to the District Court's power to issue such injunction pending final determination of the merits, and to punish violations thereof as contempt regardless of whether a permanent injunction is issued or ultimately set aside on appeal. *United States v. United Mine Workers, supra,* at 290-292. Consequently, as to the instant convictions on Counts 1, 4 and 5, which concern violations of the preliminary injunction, there is no possibility of any attack on the decree even on grounds of lack of fundamental jurisdiction.

2. The District Court Properly Construed the Federal Food, Drug, and Cosmetic Act in Issuing the Injunctions Here Involved.

With respect to the permanent injunction issued on consent, it has been shown that appellants may not now call upon this Court to determine the correctness of the District Court's construction of the reach of the statute. As has been demonstrated, the District Court had jurisdiction over the subject matter and the parties, the only permissible points of inquiry here with respect to the injunctions. However, we shall briefly set forth what we consider to be the rationale fully supporting the lower court's decision in issuing the injunctions.

By enacting the various subsections comprising Section 502 of the Act (21 U. S. C. 352), Congress clearly sought to develop reasonable and effective safeguards for the public in its use of drugs. The statute is affirmative in its demand that the labeling of a drug bear adequate directions for use, supplying the consumer with information essential to intelligent lay use. In House Report No. 2139, 75th Cong., 3d Session, page 8, the House Committee on Interstate and Foreign Commerce stated:

> "Other provisions of section 502 are designed to require the labeling of drugs and devices *with information essential to the consumer.* The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, *it is intended to make self-medication safer and more effective.* For this purpose provisions are included in this section requiring the appropriate labeling of habit-forming drugs, *requiring that labels bear adequate directions for use,* and warnings against probable misuse, and setting up appropriate provisions for deteriorating drugs." (Emphasis added.)

It is difficult to conceive of any information which could be more essential to the consumer regarding a drug which he can purchase without a physician's prescription than a statement or enumeration of the disease conditions for which the drug is to be used. Indeed, without such statement or enumeration no directions for the use of such a drug can be considered adequate under this statute.

The statutory words "adequate directions for use" cannot be construed *in vacuo,* but must be considered in relation to the information they convey to the lay public and to the efficient administration of the statute. Labeling not only serves to inform the ultimate consumer, but also performs the vital function of providing a means of determining compliance with, or violation of, the Act. *McDermott v. Wisconsin,* 228 U. S. 115, 132 (1913); *Arner Co., Inc., v. U. S.,* 142 F. 2d 730, 734 (C. C. A. 1, 1944), *cert. denied* 323 U. S. 730. How can the adequacy of mechanical instructions for the intake or application of a drug be ascertained for enforcement purposes except in relation to specific diseases, an enumeration of which must form an integral part of the directions for use?

How could it possibly be known whether certain directions for the use of a drug are adequate unless it is known what the drug is to be used for? Unless the statutory requirement of adequate directions for use in the labeling is a futility, the directions in the labeling must refer to the use of the drug in specifically enumerated conditions of disease and must lead to the effective use of the drug in the treatment or cure of such specified conditions. Furthermore, where a drug is offered to the public in newspaper advertising for certain disease conditions, it is no imposition upon the legitimate manufacturer to require him to state all of those conditions in the labeling

together with directions adequate for its use in those conditions.

In *United States v. Dotterweich,* 320 U. S. 277, 280 (1943), the Supreme Court enunciated a rule of construction for this statute which is particularly appropriate here:

> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. *Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of Government and not merely as a collection of English words.*" (Emphasis added.)

And in *United States v. Antikamnia Chemical Co.,* 231 U. S. 654, 665, 667 (1914), a case arising under the Food and Drugs Act of 1906, which preceded the instant legislation, the Supreme Court pointed out:

> "The purpose of the act is to secure the purity of food and drugs *and to inform purchasers of what they are buying.* Its provisions are directed to that purpose and must be construed to effect it."
>
> * * * * * * * *
>
> *"The purpose of the law is the ever insistent consideration in its interpretation."* (Emphasis added.)

See also pronouncements of this Court in *Research Laboratories, Inc., v. United States,* 167 F. 2d 410, 421 (C. C. A. 9, 1948), *cert. denied* ..... U. S. ..... (Oct. 18, 1948).

As we have shown, one of the purposes of Section 502(f)(1) (21 U. S. C. 352(f)(1)) is to assure that lay use of a drug in self-medication will be safe and efficacious

in those conditions or diseases for which the drug is offered to the public. If this section were to be interpreted as authorizing the omission from the labeling of the conditions of disease for which the drug is offered, it would result in the creation of a serious defect in the statute permitting the very mischief intended to be redressed. Any worthless drug could then use the channels of interstate commerce with impunity, not being required to come out in the open with therapeutic representations in the labeling which would of necessity be false and misleading.

On the basis of the foregoing impelling considerations, we submit that the District Court was eminently sound in its construction of the statute leading to the issuance of the injunctions challenged by appellants. Appellants' attempts to discover loopholes in the law are typical of similar efforts by other purveyors of worthless drugs. In *Research Laboratories, Inc., v. United States,* 167 F. 2d 410, 423 (C. C. A. 9, 1948), *cert. denied* ..... U. S. ..... (Oct. 18, 1948), this Court declared that it would best serve the public interest to keep the drug "Nue-Ovo" off of the market altogether. Even while the Court was writing this opinion, and apparently in anticipation of this decision, Research Laboratories shipped Nue-Ovo with labeling that stated no disease conditions. A seizure action under 21 U. S. C. 334(a) in the Southern District of California resulted in condemnation of the Nue-Ovo on May 13, 1948, on the ground that the labeling failed to bear adequate directions for use in that it failed to reveal the diseases or conditions for which the drug would be

effective when used as directed. (No. 7418-WM Civil.) Thus the District Court effectively complemented the decision of this Court by construing 21 U. S. C. 352(f)(1) along the lines urged by the Government here and thereby prevented nullification of this Court's ruling.

Appellants argue vigorously that the consent decree of injunction was an improper and unconstitutional attempt to control newspaper advertising. While we submit that, for the reasons previously mentioned, this point is not properly raised here, it is obvious from a mere reading of the injunctions that they *in no way regulate appellants' newspaper advertising.* Under the terms of the injunctions, appellants can say whatever they wish in their advertising. The injunctions merely require the *labeling* of their products to enumerate all of the disease conditions for which the products are offered in the advertising, together with adequate directions for their use in each of such conditions.

Violation of the injunctions resulted from appellants' referring to only *four* disease conditions in the labeling of the oil which they subsequently shipped interstate, though the advertising extolled its beneficial virtues in *twelve* disease conditions.

Thus, on the merits it is clear that the injunctions were fully authorized by the statute. In any event, however, there can be no doubt that the District Court had basic jurisdiction over the subject matter and the parties in issuing the injunctions. Under settled principles, examination of such jurisdiction, at most, is the only permissible inquiry in the present proceeding.

C. Defendants Violated Both the Letter and the Spirit of the Injunctions.

Defendant Colgrove is a graduate of a law school. [R. 65.] It is plain from the record that he understood precisely what the Court intended by the terms of the injunction. Upon issuance of the injunction, he promptly revised the label of his product to enumerate *four* disease conditions. [R. 59, 22.] He also changed the advertising so as to keep in large type only those same *four* disease conditions. [R. 59-60; Deft. Ex. B, R. 29.] But in glowing testimonial reports from clinics, doctors, druggists, and users, his advertising continued to offer the oil for *twelve* disease conditions.

In explanation, defendant Colgrove stated he had carefully analyzed the advertisement in the light of the injunction. [R. 63.] He added:

> "I relied upon the common sense conclusion that I was only advertising those diseases that are in the large type, and my literal interpretation of 'prescribed, recommended, and suggested,' the label not carrying any specific references to those diseases [enumerated in testimonial part of the advertising] and no specific references as to the instructions as to the use for those particular conditions under those names."

In other words, defendant Colgrove felt that as to the four disease conditions for which he offered the product in large type at the top of his advertisements, he *was* "prescribing, recommending, and suggesting" them, and it was therefore necessary that the labeling specifically refer to them. However, as to the additional *eight* disease conditions for which the product was held out as a cure in the testimonial part of the advertisement, Colgrove's

legal training told him he was in the clear. On cross-examination he testified as follows [R. 64-65]:

> "Q. But it is a fact, although deleting 'Acne' from the large print, it does appear in the testimonial part of the advertisement, is that right? A. That is true, but it is not as advertised. *Those things are psychologically cumulative and supportive. They were not definitely advertised.*
>
> Q. Is it your position that the large type at the top of the advertisement constitutes 'prescribing, recommending, and suggesting' but that the material which appears in the rest of the advertisement does not constitute 'prescribing and suggesting'? A. *I did not prescribe for any of the material in the rest of the advertisement.* That is one of your allegations.
>
> Q. You say you were not 'prescribing.' Were you 'recommending and suggesting' only? Is that the point? A. *I was not 'prescribing, recommending, and suggesting.' I was conforming with the decree, in my opinion, according to my literal interpretation of it.*" (Emphasis added.)

According to defendant Colgrove's dictionary studies [R. 61-62], he was not "prescribing" the oil for any remedy when he was merely quoting from excerpts of allegedly scientific reports, and letters of satisfied users. But in *United States v. John J. Fulton,* 33 F. 2d 506 (C. C. A. 9, 1929), this Court had occasion to rule upon a closely related argument. In that case, the labeling referred to testimonial letters from physicians asserting the curative value of the drugs involved in the treatment of diabetes and Bright's disease. On page 507 this Court rejected the argument in these words:

> "The point of the exception is that nowhere in the label, wrapper, or attending circular does the pro-

prietor or shipper make any direct statement or representation that the drugs are of curative or therapeutic value. In each case there is the statement, 'we have received many letters from physicians reporting,' followed by what is represented to be the substance of such 'reports,' which admittedly would tend to engender a belief to persons suffering from diabetes or Bright's disease, that the use of the drugs would likely afford them relief. Unless we discredit their mental competence, such, we must presume, was the intent and expectation of the proprietors. Their contention is that they have such letters or reports and that that fact constitutes a complete defense whatever may be the character of the drugs. But if, as is alleged, the drugs are worthless, *the proprietors cannot escape responsibility by hiding behind the phrase 'the doctors say.'* Couched in such language undoubtedly the printed matter makes a more persuasive appeal to the credulity of sufferers from these diseases than if the representations thus implied were made directly upon the authority alone of the proprietors, and for that reason they are not less but more obnoxious to the law." (Emphasis added.)

We submit that by deliberately including in their advertising excerpts of letters purporting to come from doctors, druggists, and users, praising the virtues of Colusa Natural Oil in the cure of twelve disease conditions, the defendants most effectively, in the words of the injunctions, "prescribed, recommended and suggested" the oil in the treatment of those twelve conditions. Having enumerated only four of those conditions in the labeling of the oil, they cannot seek refuge in the specious argument that as to the other eight conditions, they were merely quoting from doctors, druggists, and users. The defendants can-

not escape responsibility for the natural meaning conveyed *and obviously intended to be conveyed* by their paid advertising.

We think the meaning of the advertisement which was spread all over the nation can be fairly stated somewhat as follows:

> "If you suffer from *any* of the diseases mentioned in this advertisement, we urge you to try Colusa Natural Oil. It has cured thousands as indicated by this mere sample of excerpts from clinical studies and reports from doctors, druggists, and satisfied users. We are so sure Colusa Natural Oil will cure you, too, *if you suffer from any of these diseases,* that we are prepared to give you your money back if it does not."

Unless this meaning was conveyed to the reader by the advertisements, the defendants who were paying for the ads [R. 53] were making a charitable contribution to the newspapers running the ads, and the ads themselves were "a waste of printer's ink." *Bradley v. United States,* 264 Fed. 79, 81 (C. C. A. 5, 1920).

We do not take issue with the proposition advanced by appellants that a decree of injunction must make it clear to the affected parties what it is that they are prohibited from doing. However, the meaning of the words used in an injunction to prevent continued violation of a law is not to be ascertained solely by dictionary perusal. Rather, their meaning is to be ascertained in the light of the issues and the purposes for which the suit resulting in the injunction was brought. In *Terminal Railroad Association*

of St. Louis v. United States, 266 U. S. 17, 29 (1924), the Supreme Court made this point clear:

> "In contempt proceedings for its enforcement, a decree will not be expanded by implication or intendment beyond the meaning of its terms *when read in the light of the issues and the purpose for which the suit was brought; and the facts found must constitute a plain violation of the decree so read.*" (Emphasis added.)

See also:

> *Lustgarten v. Felt & Tarrant Mfg. Co.,* 92 F. 2d 277, 280 (C. C. A. 3, 1937).

It is obvious in the case at bar that the purpose for which the injunction was sought was to prevent further interstate shipments of Colusa Natural Oil unless its labeling (1) enumerated all of the disease conditions for which it was *held out* in its newspaper advertising as efficacious, and (2) bore directions adequate for the use of the oil in each of those conditions. [R. 2-3.] The words "prescribed, recommended, and suggested" were employed by the Court to accomplish that objective. As shown by the excerpts from defendant Colgrove's testimony, set out above, the Court's purpose was well understood by Colgrove. Nevertheless, Colgrove consciously and deliberately undertook to tear the single word "prescribe" out of its context and sought to give it an "interpretation" [R. 61-2, 65], which would enable him to continue to carry on the very activity at which the injunctions were aimed, and which would at the same time immunize him from punishment for violation of the injunctions.

Defendant manifestly set about to devise a rationalization for a scheme to thwart the District Court's orders.

Courts are not disposed to look with favor upon such enterprises. In *Rodgers v. Pitt,* 89 Fed. 424, 429 (C. C. Nevada, 1898), an opinion which well describes the attitude of courts generally toward this type of attempted evasion, the Court declared:

> "The defendant in this case was bound to obey the injunction, and when he interfered with the court's order, he was acting at his peril. He certainly ought not to have acted upon his own judgment as to what his rights were, when it was manifest that his acts would, at least, amount to a technical violation of the terms of the injunction. It was not for him to set up his own opinion as to the meaning and effect of the injunction. If he entertained any doubt as to what he might do without violating the injunction, he should have applied to the court for a modification of the injunction, or for the privilege of doing certain acts, which, by the advice of counsel, he claims he had a right to do.
>
> * * * * * * * *
>
> "The belief, motive, or intent of the defendant not to violate the injunction does not excuse him if in fact his acts resulted in a violation of it. The breach of the injunction consists in doing the forbidden thing, and not in the intention with which it is done. * * *
>
> * * * * * * * *
>
> "Courts are always disposed to allow a fair latitude of construction as to the terms of the injunction, and in many cases only require that it should be obeyed in its spirit, so that no injury should be occasioned to the complaining party. *But they are never inclined to look with any degree of indulgence on schemes which are devised to thwart their orders. Any person who has been enjoined, who undertakes to see how*

far he can go or what he may do without crossing the prohibited line, places himself in a dangerous condition, and is always liable to be deemed guilty of contempt; for his own judgment may be so warped by his feelings or necessities that he is liable, even unintentionally, to overstep the legal bounds." (Emphasis added.)

We submit that in the instant case, defendants clearly understood the full scope of the words used by the District Court in the injunctions, and deliberately transgressed both the letter and the spirit of the Court's mandate.

D. Defendants Were Not Deprived of Any Procedural Rights in the Contempt Proceedings.

Appellants' Brief raises a multitude of points regarding alleged procedural defects in the proceedings below. (App. Br. 29-34.) None has merit.

(1) The allegation is made that it was not clear whether the proceeding was criminal or civil. The proceeding was instituted as an "Information *Re* Contempt (Criminal)," brought in the name of the United States, and the last paragraph of each Count in the Information specifically charges that the defendants are "in criminal contempt." [R. 2-15.] Also, the Order to Show Cause ordered the defendants to appear and show cause why they should not be adjudged "in criminal contempt." [R. 16.] The stipulation of facts entered into refers to "the parties to this criminal contempt action." [R. 24.] Just how the criminal nature of this proceeding could have been made clearer is difficult to conceive. In *United States v. United Mine Workers of America, supra,* at 297, the Supreme Court held that the defendants were quite aware that a criminal contempt was charged despite the fact that the words

"criminal contempt" did not appear either in the petition or in the rule to show cause.

(2) Appellants complain that "the proceedings started out as a civil proceeding with an Order to Show Cause being issued against the defendants." (App. Br. 29.) But Rule 42(b) of the Federal Rules of Criminal Procedure, which appellants quote (App. Br. 4-5), *expressly* authorizes the initiation of a criminal contempt proceeding by "an order to show cause." In the *United Mine Workers* case, *supra,* at 297, the Supreme Court affirmed convictions of criminal contempt based upon a rule to show cause.

(3) Appellants assert that there was no arraignment or plea and therefore the proceedings were void. (App. Br. 29-30.) However, Rule 42 of the Federal Rules of Criminal Procedure, which prescribes the special procedure to be followed in criminal contempts, does not require arraignment and plea. Moreover, it is settled that even the total absence of an arraignment is not a fatal defect in a criminal prosecution where the accused, as here, have had sufficient notice of the accusation and an adequate opportunity to defend themselves. *Garland v. State of Washington,* 232 U. S. 642, 645 (1914.)

(4) Appellants claim they were denied a trial "in the full sense of that term." (App. Br. 30-31.) As to adequacy of notice, there can be no question. Actually, the Criminal Information was filed on October 2, 1947 [R. 15]; the Order to Show Cause issued on October 3, 1947. [R. 16-17.] Yet hearing on the Order to Show Cause was deferred at defendants' request until December 8, 1947. [R. 45-55.] At the hearing, the District Court found that the alleged contempt had not been sufficiently purged, and asked defendants whether they wanted a jury trial. [R. 53.] Defendants through counsel stated that

a Court trial would be satisfactory and then executed a written waiver of jury trial and special findings. [R. 53, 25.]

At the hearing on the Order to Show Cause, the Government's attorney introduced a stipulation which reads as follows [R. 46, 24]:

"STIPULATION.

It is hereby stipulated and agreed by and between the parties to this criminal contempt action:

(1) That all of the facts set forth in the Criminal Information are true, except that it is not admitted that the advertisements referred to in said Information prescribe, recommend and suggest Colusa Natural Oil in the treatment of poison ivy, poison oak, bed sores, acne, ringworm, scaley red face, burns, piles and itch.

(2) That the attached newspaper advertisement taken from page 8 of the June 12, 1947, issue of the The Ridgewood Herald-News, Ridgewood, New Jersey, and identified as Exhibit A, is typical of the advertisements referred to in said Information.

(3) That the label on the bottle of Colusa Natural Oil identified as Exhibit B is representative of the labels referred to in Counts 1-8 of the Information.

(4) That the label on the bottle of Colusa Natural Oil identified as Exhibit C is representative of the labels referred to in Count 9 of the Information."

By express agreement of counsel at the hearing, this stipulation and the exhibits to which it referred were "deemed in evidence upon the trial." [R. 55.]

Trial was set for December 19, 1947, a date satisfactory to defense counsel. [R. 54-55.] At the trial, defense counsel again agreed that the stipulation and exhibits would be deemed part of the record for the purpose of the trial. [R. 56.]

Appellants are in error when they state the injunctions were not introduced into evidence at the contempt trial. [R. 31.] The Criminal Information sets forth the pertinent portions of the injunctions verbatim [R. 2-3] and defendants stipulated (with one reservation not pertinent here), that "all the facts set forth in the Criminal Information are true." [R. 24.]

(5) Appellants argue that "there can be no more than one count for contempt." [R. 34.] The eight counts on which appellants were convicted are expressly based upon eight separate interstate shipments of Colusa Natural Oil, each of which was in violation of the preliminary or the permanent injunction. [R. 2-14.] The District Court, having found defendants guilty on Counts 1-8, sentenced each defendant separately on each count. [R. 34-38.] As to the individual defendant Colgrove, the Court imposed a sentence of fine *or* imprisonment on each count, execution of the imprisonment sentence being suspended during a probationary period. On no count was a sentence of both fine and imprisonment imposed.

The District Court's power to punish for contempt in this case stems from its inherent and general statutory

power contained in Title 28, Section 385,[3] United States Code, to punish for contempt the disobedience by any party of any lawful decree of the Court. That provision authorizes the Courts "to punish, *by fine or imprisonment, at the discretion of the Court,* contempts of their authority."

It has been held that such a contempt is punishable either by fine or by imprisonment, but not by both. *In re William v. Bradley,* 318 U. S. 50 (1943). This was followed here.

It has also been held that where a person is convicted on a number of contempt charges, he may, as in this case, be fined on some and imprisoned on others.

> *Rapp v. United States,* 146 F. 2d 548, 549 (C. C. A. 9, 1944);
>
> *Hoffman v. United States,* 13 F. 2d 278, 279 (C. C. A. 7, 1926).

From these authorities, it is clear that defendants, having been convicted on eight different criminal contempt counts arising out of eight separate and distinct transactions, were properly subject to a *fine or imprisonment* on each count, the nature and extent of *each* such sentence being discretionary with the District Court.

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[3]Section 302(b) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. 332(b)] declares that the trial in a criminal contempt proceeding such as the instant one shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to 28 U. S. C. 387 (the Clayton Act). Since only the practice and procedure of the Clayton Act are adopted for the purposes of trial, the *power* of the District Court to act at all is derived from its inherent authority to punish criminal contempts, as qualified by 28 U. S. C. 385. It has already been held that only a limited portion of the Clayton Act is applicable to contempt proceedings under 21 U. S. C. 332(b). *United States v. Dean Rubber Mfg. Co.,* 72 Fed. Supp. 819 (W. D. Mo., 1947).

E. The Sentences Imposed Were Not Excessive.

Under 28 U. S. C. 385, the character and extent of punishment is entirely discretionary with the Court. *Creekmore v. United States,* 237 Fed. 743, 752 (C. C. A. 8, 1916), *cert. denied* 242 U. S. 646; *Oates v. United States,* 233 Fed. 201, 208 (C. C. A. 4), *cert. denied* 242 U. S. 632; *United States ex rel Brown v. Lederer,* 140 F. 2d 136, 139 (C. C. A. 7, 1944), *cert. denied* 322 U. S. 734. See also the Supreme Court's declaration in the *United Mine Workers* case, *supra,* at page 304, distinguishing between the criteria applicable in imposing sentence in civil and in criminal contempts.

At the outset of our argument in this brief, we informed this Court that the printed record does not contain certain voluminous material bearing upon the previous activities of defendants with which the District Court was familiar and which had been made part of the record below at the time sentence was imposed, the omission of which greatly shortened the printed record on appeal and thus considerably reduced the cost to appellants. This omission, was brought about by counsel's representation that he intended to raise no issue on appeal as to excessiveness of penalty.

Even without the complete record, however, it is clear from the printed record and from the other sources to which we have referred and of which this Court may take judicial notice, what considerations prompted the sentences imposed by the District Court. Obviously, the District Court was impressed by the defendants' long history of law violations, and constant scheming for ways and means

to circumvent not only the food and drug law but also other laws. See, for an example of violation of another law, *Colgrove et al. v. Lowe et al.*, 343 Ill. 360, 175 N. E. 569, *cert. denied* 284 U. S. 639, where an insurance scheme of defendant Colgrove was held illegal.

Furthermore, as to the defendants' ability to pay the fines assessed, Colgrove testified that the two column advertisement published from time to time in at least fifty-eight newspapers all over the country "had been a successful producer." [R. 59.] At the time of the sentencing, he also indicated the substantial revenues which had been derived from the sale of Colusa Natural Oil.

Under the circumstances, we submit that the sentences imposed by the District Court were far from excessive, and well within the limits of its discretionary power. The total fine of $9000 represents only a fraction of the illicit profits which defendants have obtained by preying upon the gullible and the sick. Moreover, the suspended jail sentence imposed upon defendant Colgrove, is probably the most effective deterrent the Court could devise to prevent further illegal activities—short of sending the defendant to jail.

VI.
Conclusion.

We respectfully submit that the judgments of the District Court in convicting and sentencing the defendants are correct and should be affirmed.

Respectfully submitted,

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